

Filovirus Animal Model Workshop

Michael G Kurilla, MD-PhD

Director, Office of BioDefense Research Affairs

Division of Microbiology & Infectious Diseases

Associate Director, BioDefense Product
Development

National Institute of Allergy and Infectious
Diseases

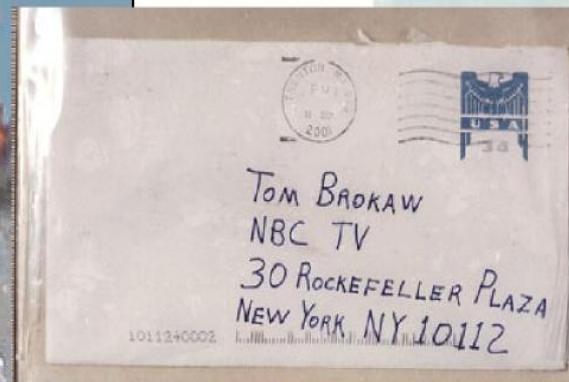
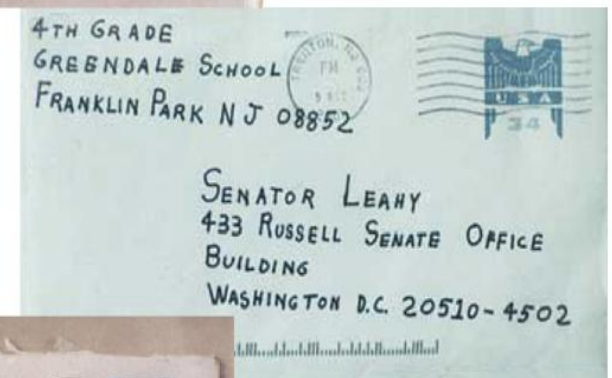
September 11, 2007



A Premature Declaration of Victory Over Infectious Diseases

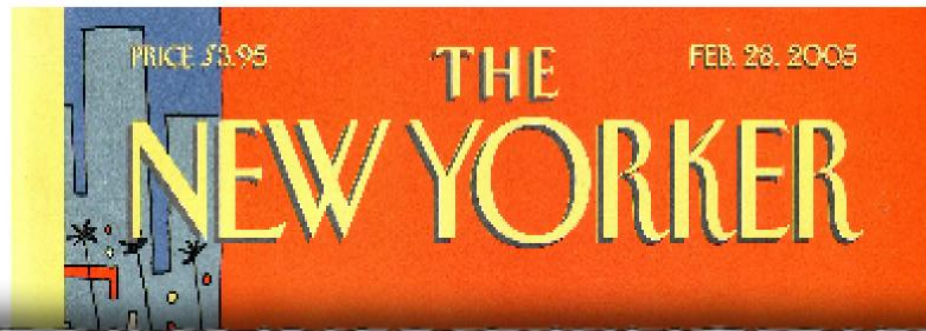
"We can look forward with confidence to a considerable degree of freedom from infectious diseases at a time not too far in the future. Indeed... it seems reasonable to anticipate that within some measurable time... all the major infections will have disappeared."

- Aidan Cockburn, *The Evolution and Eradication of Infectious Diseases*, 1963.



SARS: A New Challenge to Global Health



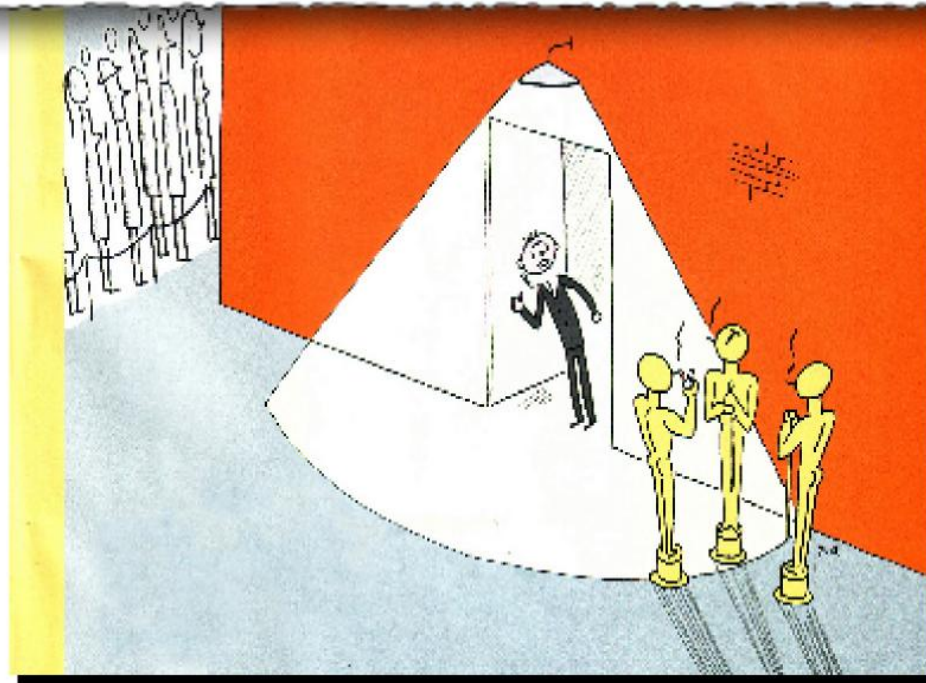


A Reporter at Large

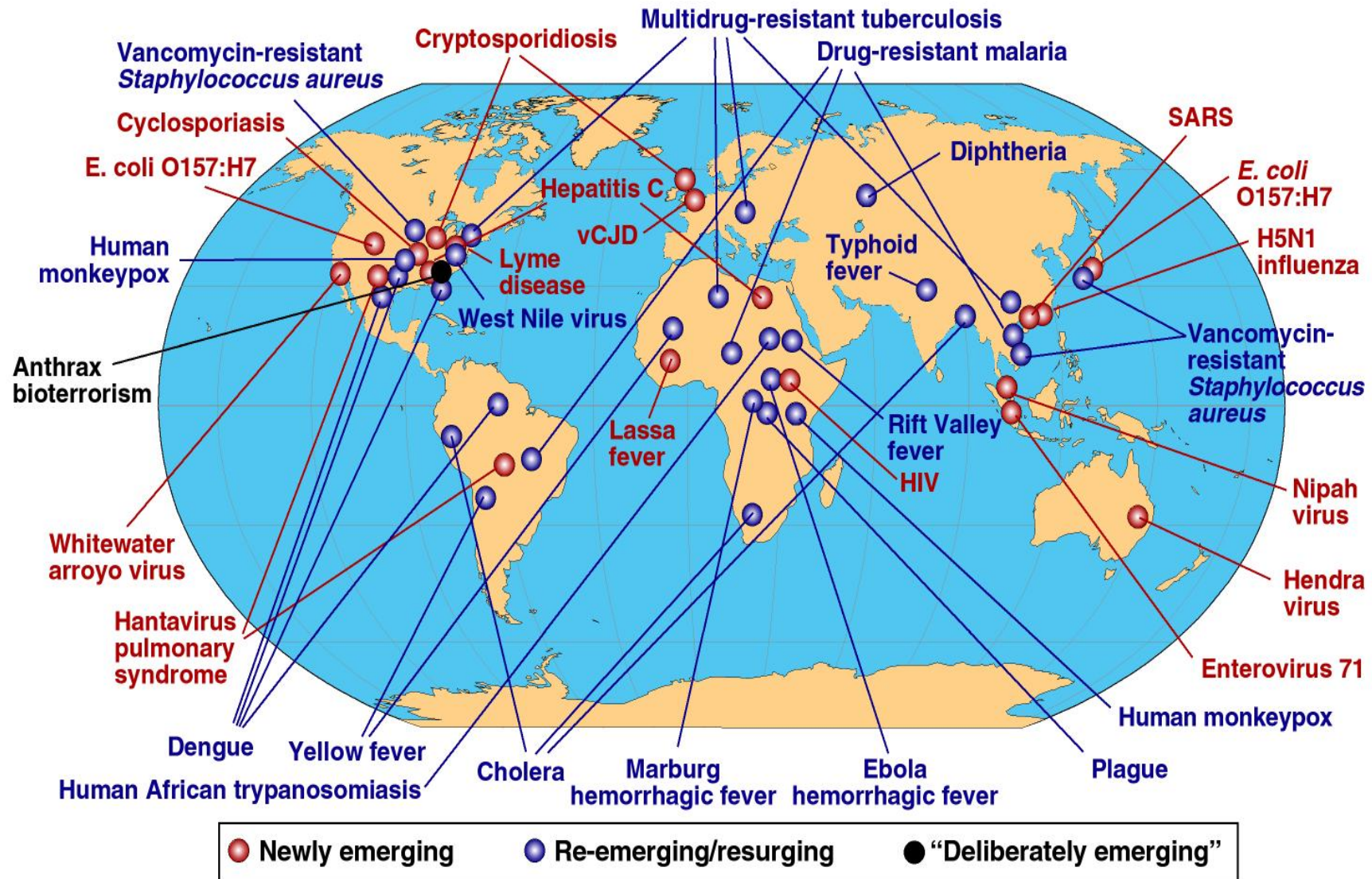
NATURE'S BIOTERRORIST

Is there any way to prevent a deadly avian-flu pandemic?

By Michael Specter



Global Examples of Emerging and Re-Emerging Infectious Diseases





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*HHS Public Health Emergency Medical
Countermeasures Enterprise (PHEMCE)*

Strategy for Chemical, Biological, Radiological and Nuclear Threats



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE IMPLEMENTATION PLAN

**FOR CHEMICAL, BIOLOGICAL,
RADIOLOGICAL AND NUCLEAR THREATS**



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
OFFICE OF PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES**

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'Animal Rule'

- Human efficacy evaluation not technically possible or ethically feasible
- Human clinical data still needed
 - Immunogenicity / PK data
 - Safety demonstration
- Approval comes with post-marketing studies and use restrictions
- Requires appropriate animal efficacy data

Integrated R&D for Product Development

